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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/581,244

05/31/2006

Keiichi Matsuhisa

2006\_0801A

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7590

02/02/2009

WENDEROTH, LIND & PONACK, L.L.P.

2033 K STREET N. W.

SUITE 800

WASHINGTON, DC 20006-1021

EXAMINER

CORNET, JEAN P

ART UNIT

PAPER NUMBER

4121

MAIL DATE

DELIVERY MODE

02/02/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/581,244	<b>Applicant(s)</b> MATSUHISA, KEIICHI	
	<b>Examiner</b> JEAN CORNET	<b>Art Unit</b> 4121	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01/07/2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/31/2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-9 are currently pending and are the subject of this Office Action. Claim 6 is withdrawn from consideration. After further examination, Claims 7-9 which should have been included with Group (I) are rejoined with Group (I) for examination, Claims 1-5 & 7-9 are presently under examination. This is the first Office Action on the merits of the claims.

### ***Priority***

This application is a national stage application of PCT/JP2004/017762 filed on 11/30/2004 claims benefit of JP 2003-403719 filed on 12/02/2003.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 & 7-9 are rejected under 35 USC § 102(b) as being anticipated by Japanese Patent (JP2000-007569) herein “569”. Published on 01/11/2000 and filed on 06/19/1998.

**Claim 1;** an aqueous suspension comprising loteprednol etabonate and methyl p-hydroxybenzoate The ‘569 patent teaches a therapeutic agent for olfactory disorder

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comprises of **loteprednol etabonate**, water, a **preservative**, an isotonizing agent, a buffering agent, stabilizer, a pH controlling agent, a thickening agent, a suspending agent, etc..(Abstract), cited in the IDS. The '569 also teaches methyl parahydroxybenzoate as an example of preservative Paragraph [0005] lines 8&9.

**Claims 1, 2;** a non-ionic surfactant is additionally contained in the aqueous suspension.

The '569 teaches anionic surfactant Paragraph [0006] line 11.

**Claims 1, 2, 4 & 8;** the suspension is a nasal-drop. The '569 teaches the sense-of-smell obstacle medical treatment agent of this invention is a nasal-drop Paragraph [0005] line 5).

**Claims 1, 2, 3, 5, 7 & 9;** the aqueous suspension is an eye-drop or ear-drop.

It is absence evidence to the contrary that the '569 disclosed a therapeutic agent for nasal drop may be identical in composition to a suspension for eye and/or an ear drop of the instantly claimed suspension. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic (re Best, **195 USPQ 430** and In re Fitzgerald, **205 USPQ 594**)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEAN CORNET whose telephone number is (571)270-7669. The examiner can normally be reached on Monday-Friday 7.30am-5.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)? If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JC/

/Patrick J. Nolan/  
Supervisory Patent Examiner, Art Unit 4121